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EXAMINER

LAMPRECHT, JOEL

ART UNIT

PAPER NUMBER

3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/713,453

Applicant(s)

VON BEHREN ET AL.

Examiner

Joel M. Lamprecht

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1/30/07 have been fully considered but they are not persuasive. Regarding the argument that Skyba does not show the phase of a cyclically varying imaging parameter relative to a physiological cycle for multiple spatial locations and highlighting spatial locations on a first image and second image associated with two different phases, the Examiner directs Applicant's attention to Col 4 Line 65 – Col 5 Line 60 where Skyba et al specifically disclose their capacity to select multiple locations, and specific phases within the heart cycle for the purpose of tracking a cyclically varying parameter which is relative to imaging, and also discloses highlighting the area of interest within the selected images. Skyba et al match the B-mode data up with ECG data, which is a sinusoidal variation throughout a heart cycle. Perfusion/reperfusion is mapped and is a valid cyclically varying imaging parameter as reperfusion will directly affect the images obtained during imaging. Also Skyba et al disclose filtering frequencies from data acquired at specific portions of the sinusoid in Col 3 Line 10-65. The frequency data from Skyba et al is added and filtered selectively so that B-mode images are able to be processed.

2. Regarding claim 4, Skyba uses mean intensity at each pixel to identify the value at the specific phase at that location. Common location values are identified throughout the acquisition to obtain a value over time, which would of course correspond to a phase in the ECG measurement. Regarding the arguments to claim 6, referrer to Col 7 Lines 12-37, regarding the arguments to claims 7 and 8 reference Col 5 Line 39 – Col 6

Line 20 where spatial locations can be outlined and acquisitions are described for different phases in the heart cycle. Regarding the arguments to the rejection of claim 11, reference the same section for the discussion of selective borders and enlargement of an area of interest in a frame of interest. Regarding the arguments for claims 23, 25 reference the discussion above regarding filtering and coupling of filtered signals to acquire data for the production of B-mode images.

3. Regarding the combination of references the Examiner would like to first point out the expected level of knowledge for one of ordinary skill in the art at the time of the invention. It would be reasonable to assume that the representation of a filter in the time domain versus that of the frequency domain should be well known to one of ordinary skill in the art. Additionally the shift of data from time to frequency domain and back should be extremely well-known to an individual performing A/D conversions within their imaging invention. Additionally, Finite impulse response filtering is defined by some difference equation which would require knowledge of stability, linear phase (frequency dependent), which would also require those implementing the filter to keep in mind the frequency response of the filter itself. The fact remains that reference to Hossack simply to illustrate that FFT and other discrete transforms are invertible and provide a very simple means for performing operations in the frequency domain which would be otherwise complicated within the time domain. The reference to Hossack was not to highlight the compression steps taken in JPEG compression, simply to illustrate that in order to read the reference to Skyba in the most reasonable light, one must take into account that frequency domain functions are well known and in the case of the FFT are

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easily invertible. Given the required knowledge and creativity base of one of skill in the art, and given the choice of sampling frequency disclosed in Skyba, as well as the pulse inversion components of (Col 4 Line 5-17) would imply that Skyba is again familiar with the fundamental frequency, the frequency domain, and harmonics. Regarding claim 10, Examiner respectfully disagrees that one of ordinary skill in the art would not find it fitting to highlight a mechanical heart in the same manner as a natural physiological heart. Regarding claim 31 (IE Col 4 Line 5-65), Sumanaweera uses harmonic data throughout to eventually acquire boundary data (Col 10 Line 39-52). Regarding claims 20 and 21 Skyba uses pulse inversion to intensify and isolate harmonic signal components from the fundamental frequency components.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 4, 5, 6, 7-9, 11, 12, 13, 15-17, 19, 22-25, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Skyba et al. (6,692,438). Skyba et al. disclose the limitations of 1a in Col 2 Lines 15-25 and 28-40 including indentifying a phase of a cyclically varying parameter relative to a physiological cycle for each of a number of

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locations in a number of image frames, 1b in Figures 5, 6a, 6b and Col 4 Lines 30-50 including displaying a number of images corresponding to image frames at different times, 1c and 1d in Col 3 Line 65 to Col 4 Line 50, and Col 2 Lines 15-25 including highlighting spatial locations in a first and second image taken at different times and in different phases. Further details of this process are located in Column 4 Line 65 – Col 5 Line 60 where the description of the available selection of phases is described.

3. Regarding Claim 2 Skyba et al. disclose the limitations in Col 3 Lines 10-42, Col 3 Line 65 – Col 4 Line 24 including matching a waveform to variation in B mode values during the cycle, and identifying the phase of a sinusoid relative to the physiological cycle.

4. Regarding Claims 4, 5 and 6 Skyba et al. disclose the limitations in Col 5 Lines 39 -60 Figures 9a and b, Col 5 line 60 - Col 6 Line 40 and Col 3 Line 65 – Col 4 Line 24 including identifying a phase for spatial locations including those comprising of pixels or single pixels, and generating B mode images as step (b) from Claim 1. Skyba et al. also disclose a method for having spatial locations darker at one phase than another from Col 4 Line 30 – Col 5 Line 60 for acquisition and Col 5 Line 60 – Col 6 Line 20 for border detection thus making one group of phase data darker than another (also see Col 7 Line 13 –37)

5. Regarding Claims 7-9 and 11 Skyba et al. disclose all the limitations in Col 5 Lines 39 – Col 6 Line 20 including highlighting spatial locations at a first range of phases and second range of phases as a constant array of data streaming from the system, and highlighting different images from the different phases. Claim 11 is

included in this rejection due to the ability of the system disclosed by Skyba et al. to individually highlight movement associated with the individual phases.

6. Regarding Claims 12, 13, and 19 Skyba et al disclose the limitations in Figure 5 where real time images are shown over multiple heart cycles and is discussed in Col 5 Line 40 – Col 6 Line 20, and Col 3 Line 55 – Col 4 Line 5 including combining frames of data from multiple cycles to represent a single physiological cycle of multiple image frames and generating 3d images for part b of Claim 1.

7. Regarding Claims 15, 16 and 17 Skyba et al. disclose all the limitations listed above specifically that their invention is for diagnosis (which would inherently imply that a patient's heart is either "sick" or is under suspicion of being "sick"), highlighting pixels in a sequence of images as a result of shifting phase intervals, and data processing by isolating information with a specific frequency band for each location as a function of waveforms (Col 3 Lines 10 – 40, Col 3 Line 54 – Col 4 Line 25), and adding information from the different frequency band to the isolated information (Col 2 Line 28-37 and Col 3 Line 54 – Col 4 Line 25).

8. Regarding Claims 22, 23, 24, and 25 Skyba et al disclose acquiring data representing contrast agents (Col 1 Line 23 - 33, generating images of intensities as a function of time (as shown above), 3d images (as shown above), and adding information from different frequency bands to the information in the frequency domain (Col 3 Lines 11 – 65).

9. Regarding Claim 28 Skyba et al. disclose acquiring ultrasound data for a plurality of spatial locations over a physiological cycle (Col 2 Lines 15 – 25, Lines 28 – 40),

matching sinusoid data with the ultrasound data for spatial locations, isolating information with at least one frequency band from information associated with different bands for each of a number of spatial locations as a function of a matched sinusoid and detecting a boundary from the data (Col 3 Line 11 –42, Col 6 Line 20 – Col 7 Line 38).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 3, 18, 20, 21, 26, 27, 29, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skyba et al. in view of Hossack et al. (6,755,787).

Regarding Claim 3, Skyba discloses all that is listed above and also implies some form of domain switching for processing of image data, but it is never explicitly mentioned. Attention is directed to the secondary reference by Hossack et al. which specifically mentions performing Fourier transforms and once the Fourier transform is performed, it is inherent that phase angle data and fundamental frequency would be known as they are basic properties that are well-known to anyone having the mathematical aptitude to perform such a transform. It would have been obvious to one having normal skill in the art at the time of the invention to have included the methods of Hossack et al. and interpret the meanings of the data into the system of Skyba et al. including the

knowledge of the fundamental frequency from the harmonic pulse inversions Col 4 Line 5-17 in order to process the image data and further diagnosis of "sick" tissues.

12. Regarding Claim 18, Skyba et al. discloses all that is listed above but does not explicitly mention performing an FFT. Attention is then directed to the secondary reference, which discloses performing FFT's in the same field of endeavor. Therefore it would have been obvious to one having normal skill in the art at the time of the invention to have included the FFT methods of Hossack et al. in the system of Skyba et al. to analyze the image data acquired.

13. Regarding Claims 26, 27 and 29 Skyba et al. disclose all that is listed above including a combination of information from frequency data to other information synchronized with that data, but do not explicitly mention adding information from a different frequency band to isolated information in the spatial domain. Attention is then directed to the secondary reference by Hossack et al. which discloses in Col 35 how data can be transferred back and forth during image processing including information from both the frequency domain and the spatial domain using FFT, inverse Fourier transforms to incorporate spatial domain data with frequency data. Therefore it would have been obvious to one having normal skill in the image processing art at the time of the invention to have incorporated the system disclosed by Hossack et al. in the system disclosed by Skyba et al. to process the image data and acquire all the desired information for diagnosis of a patient.

14. Claims 20, 21, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skyba et al. in view of Sumanaweera et al. (6443894).

15. Skyba et al. disclose all that is listed above but fail to mention boundary detection based on amplitude or phase data directly even though edge detection and tissue definition is mentioned, it is not discussed as a processing technique. Attention is then directed to the secondary reference by Sumanaweera et al, which teaches a broad range of boundary detection or edge-detection methods from Col 10 Line 23 – Col 11 Line 27 including detection of the boundary from amplitude and phase data. Therefore it would have been obvious to one having normal skill in the art at the time of the invention to have used the methods of processing disclosed by Sumanaweera et al. in the image processing art to detect boundaries in the system disclosed by Skyba et al. because edge detection enables a clear diagnosis of tissue types and ailments by the physician.

16. Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skyba et al. in view of Chiang et al. (6969352). Skyba et al. disclose all that is listed above but do not mention synchronizing their method with a pacemaker or highlighting movement of a mechanical heart contraction wave during a heart cycle. Attention is then directed to the secondary reference in the same field of endeavor, which suggests such an ultrasonic imaging system for pacemaker monitoring, or artificial heart device implantation (Col 4 Lines 43 – 63). It would have been obvious to one having normal skill in the art at the time of the invention to use the method of pacemaker monitoring ultrasound with the highlighting movement of a heart contraction during the physiological cycle as disclosed by Skyba et al. due to the fact that implanted

or artificial devices require the same attention as natural human hearts and provide the same if not worse possibility for "sickness" or failure.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML
7/31/07


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